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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/637,962	08/11/2000	Lawrence H. Thompson	500731.01	8001

27076 7590 02/05/2004

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EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 02/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/637,962	THOMPSON, LAWRENCE H.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *66,68,76-85,117-127,129 and 130* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *66,68,76-85,117-127,129 and 130* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Due to the necessity of addressing new grounds of rejection, the finality of the previous Office Action (16 June 2003) is hereby withdrawn in view of substantial new issues, as set forth below.

Status of Application, Amendments and/or Claims

The amendment filed 15 December 2003 has been entered in full. Claims 66, 68, 76-85 and 117-127, 129 and 130 are under examination.

Withdrawn Objections And/Or Rejections

The rejection of claims 66 and 117 under 35 U.S.C. § 112, first paragraph, written description, new matter, as set forth at pages 2-5 of the previous Office Action (16 June 2003) is *withdrawn* in view of the amendment (15 December 2003).

The rejection of claims 66-68, 76-85 and 117-130 under 35 U.S.C. 112, first paragraph, scope of enablement as set forth at pages 5-9 of the previous Office Action (16 June 2003) is *withdrawn* in view of the amendment (15 December 2003).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 66, 68, 76-85, 117-127, 129 and 130 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kveder *et al.,* Farmacevtski Vestnik 47/SPEC. ISS. pages 163-171, (1996). The Examiner is submitting the article (written in Slovene) and the translation.

The instant claims are drawn to a method for treating an anemic condition in a subject, the method comprising administering to the subject a therapeutic amount of a recombinant erythropoietin produced in baby hamster kidney cells, the recombinant erythropoietin consisting of Epoetin Omega wherein the amount of recombinant erythropoietin administered is selected to provide a therapeutic benefit within a treatment period, and wherein the subject is non responsive (or adversely effected) when treated with a therapeutic amount Epoetin Alfa or Beta.

Kveder *et al.* teach a clinical trial with epoietin omega (abstract). Kveder *et al.* teach that epoietin omega is produced by the Powel recombinant method *in vitro* from baby hamster kidney cells (page 7, 4th paragraph). Kveder *et al.* teach the primary objectives such as raising hemoglobin and hematocrit (page 8, 1st paragraph). Patients included those who had required hemodialysis twice or three times per week and who also had hemoglobin levels below 85 grams per liter or below 90 grams/liter when they had been dependent on frequent transfusions (page 8, last paragraph-page 9). Epoietin omega was administered subcutaneously in an average dose of 25 to 75 IU/kg of weight twice or three times a week. Kveder *et al.* teach the course of average weekly dosage during treatment with epoietin omega (page 11). Kveder *et al.* state that the clinical trial of efficacy and tolerance for treatment with erythropoietin omega showed

that it is possible to achieve a correction in anemia within a relatively short period of time in patients with chronic kidney failure who are being treated with dialysis. The doses need to accomplish the stated objectives were within the range that had been anticipated by the manufacture in a large majority of patients (page 15). Since a compound and all of its properties are inseparable (*In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)), the epoietin omega would be expected to increase RBC, HCT, hemoglobin and vigor. Kveder *et al.* do not teach the administration of epoietin omega in subjects who are non responsive or adversely affected when treated with a therapeutic amount of epoietin alfa or beta.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Kveder *et al.* to make the instant method of treating subjects with epoietin omega, who are non responsive or adversely affected when treated with a therapeutic amount of epoietin alfa or beta. Kveder *et al.* teach the side effects (muscle aches, flu-like symptoms) associated with administration of recombinant human erythropoietin (page 5). The motivation and expected success is provided by Kveder *et al.* who state that the clinical trial of efficacy and tolerance for treatment with epoietin omega showed that it is possible to achieve a correction in anemia within a relatively short period of time in patients with chronic kidney failure who are being treated with dialysis. Kveder *et al.* state that patients tolerated epoietin omega treatment well. One patient had an allergic reaction and only one patient reported pain during subcutaneous administration. Thus, it would be obvious to one skilled in the art at the time the invention was made to substitute epoietin alfa or beta

with a different form of recombinant human erythropoietin, epoietin omega, in patients who are non responsive or adversely affected when treated with epoietin alfa or beta. The adjustments of other conventional working conditions (i.e. titration periods and time) are deemed a matter of judicious selection and routine optimization, which is well within the purview of the skilled artisan.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RMD
February 2, 2004

YVONNE EYLER, PH.D
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